AIR VALVE FOR EXTERNAL PROSTHESIS

The disclosures of the following applications, in their entirety, are incorporated herein by this reference: prior U.S. Non-Provisional application Ser. No. 13/206,489, filed Aug. 9, 2011, U.S. Non-Provisional application Ser. No. 12/364,511, filed Feb. 2, 2009 and issued as U.S. Pat. No. 7,993,413 on Aug. 9, 2011, U.S. Non-provisional application Ser. No. 11/527,752, filed Sep. 25, 2006 and now abandoned, Provisional Application Ser. No. 60/719,785, filed Sep. 24, 2005, and Ser. No. 61/024,913, filed Jan. 31, 2008; and U.S. Non-Provisional application Ser. No. 12/826,633, filed Jun. 29, 2010.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to prosthetics, and more specifically to a valve device for control of pressure in an external prosthetic such as may be used on a residual limb.

2. Related Art

Gravitational and other forces tend to cause separation between a prosthetic limb and a residual limb. This happens, for example, during the swing phase of the gait, when a prosthetic leg is additionally subjected to centrifugal forces. The manner in which an artificial limb is suspended and/or attached to the residual limb determines the amount of control an amputee has over the prosthesis. Patients have routinely worn a variety of belts, straps, cuffs and harnesses to prevent the prosthetic limb from separating from the residual limb, but such devices are inconvenient and tend to cause chafing against the patient's body, giving rise to sores and abrasions.

It has long been appreciated that differential air pressure, often referred by those of skill in the art as "suction," may be utilized to retain or suspend, or assist in retaining or suspending, a prosthetic limb on a patient's residual limb. "Suction suspension" typically involves a hard socket and a cooperating socket liner positioned between the residual limb and the prosthetic socket. The liner is rolled onto the residual limb for a suction, slight compression, and/or gripping connection of the inner gel layer (or otherwise tacky layer) of the liner to the skin of the residual limb. The liner-covered limb is then inserted into the prosthetic socket, and the outer surface/layer of the liner preferably forms a suction, grip, or other interference fit to the socket to interfere with the socket falling off the limb.

Socket liners frequently have been called "suction liners," "gel liners," "roll-on liners" or "suspension liners" and include the "first generation" of gel-layer-only liners, and also the modern "second generation" liners currently preferred by most wearers of prosthetics. These modern liners "second generation" liners typically comprise a thin textile/fabric outer layer that is fixed to the gel-like inner layer (silicone, urethane, or other rubbery/gel-like material). Thus, the second generation of liners is similar to the first generation in its connection to the residual limb, but its connection to, or cooperation with, the socket is modified by the presence of the textile/fabric layer. The term "suction liner" began with the first generation liners, which featured the gel layer contacting both the residual limb (liner's inner surface) and the socket (liner's outer surface), and, therefore, could be used to create a fairly high amount of pressure differential between the inside of the socket (in the "well" of the socket) and the surrounding ambient air. The terms "suction liner" and "suction socket" are still used by many manufacturers, prosthetic technicians, insurance and medicare/medicaid entities, and wearers of prosthetics, even though the modern "second generation" liners, with their textile/fabric outer layers, typically do not form what would be called "true" or "pure" suction with the socket, but rather form what should more accurately be called a "partial suction" with the socket, as further discussed below. See the discussion of suction liners in Janusson, et al. (U.S. Pat. No. 6,706,364) and Janusson, et al. (U.S. Pat. No. 6,626,952).

The preferred gel-like inner layer of a limb liner grips the limb to such an extent that it needs to be rolled-onto the limb from a rolled-up "doughnut" form, rather than pulled on like a sock. When rolled-on, there is little, if any, air remaining between the inner surface of the roll-on liner and the limb, and the roll-on liner is snug against the limb all the way around the circumference of the limb. Also, the inner surface of the roll-on liner is of such material and tacky texture that air will not be able to, or be very unlikely to, enter between the roll-on liner and limb. Thus, the roll-on liner may be said to form a suction fit and/or a slight compression fit with the limb. A distal force on the liner, such as caused by the swing of a gait with a prosthetic leg, may tug on the roll-on liner but typically does not loosen, lower, or remove the liner from the limb.

The hard socket is usually laminated or otherwise fabricated from polyethylene, polypropylene, or other copolymers, for example, and is donned over the liner and the residual limb. A "true" suction fit (allowing high suction, greater amount of vacuum) will be more likely to form, between the liner-sheathed limb and the interior of the socket, if: a) the liner exterior surface is smooth and flexible enough to conform to the contours of the residual limb, for example, non-air-permeable material such as the silicone, urethane, or other rubbery or gel-like material; b) the interior surface of the socket is also smooth and non-air-permeable; and, of course; and c) if the socket has no un-sealed holes or apertures. A "partial" suction fit (allowing lower suction, low amount of vacuum) is more likely to form in the case of modern "second generation" liners, because not all of these conditions are met. For example, although there is preferably a close fit between the contour of the liner-cover limb and the contour of the internal surface of the socket, which provides significant resistance to air entering the socket via the top opening of the socket, still, some air slowly enters the socket through the top of the socket or through a seam, connection, lock or other aperture in the socket, especially during the swing portion of the wearer's gait and during periods of relative inactivity. Air entering the socket through one or more of these locations may then slowly flow through or past the fabric layer of the modern liners, into the distal area of the interior of the socket, that is, the well of the socket.

The "partial" suction fit tends to be more comfortable for many wearers that a "true" or "full" suction fit. In other words, a textile/fabric-covered liner and the resulting "partial" suction tends to be more comfortable than the stronger "tugging" on the residual limb created by the "full" suction of first generation, gel-layer-only liner. A partial suction suspension, however, is difficult to control due to the dynamics of use of the prosthetic. The process of walking and other weight-bearing, therefore, comprises the steps of pushing the limb further into the socket, followed by the swing portion of the gait that tends to pull the socket off the limb. A one-way "check" valve, typically called an "expulsion valve", may be added to the hard socket to allow air expulsion (of the air leaking into the socket) with each weight-bearing step, while preventing air to flow through (in the reverse direction) through the valve into the socket well during the swing portion of the gait. Thus, an object of the expulsion valve is to maintain a slight negative pressure (partial suction) relative to ambient once the socket has been fitted on the residual limb